



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION
OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION (7505P)

FEE

DOCUMENT CONTAINS CONFIDENTIAL BUSINESS INFORMATION

DP BARCODE No.: D464769 FILE SYMBOL No.: 62719-TAA PRODUCT NAME: GF-5040
DECISION No.: 580826; ACTION CODE: R310; FOOD Use: Yes; COMPANY: Corteva Agriscience LLC.
E-Submission #: 70827. Submission #: 1079754.

DATE OUT: August 23, 2022

SUBJECT: New End Use Product Chemistry Review of "GF 5040"

FROM: William Herald / Microbiologist/Chemist REHS/Registered Sanitarian *W. Herald*
Product Chemistry Team
(CITAB) RD (7505P)

THROUGH: Shyam Mathur *sbmathur* 8-24-2022
Product Chemistry Team Leader
CITAB/RD (7505P)

TO: Aleah Holt / Emily Schmidt, PM 25
Herbicide Branch/ RD (7505P)

INTRODUCTION:

Registrant has submitted their application for the registration of the new end use product "GF-5040". In support of the registration application, the Registrant had submitted 830 series group A and group B product chemistry data with MRID No's. 51661401-2; the Basic CSF formulations (dated 12/13/2021). CITAB has been asked to determine acceptability of the proposed CSF and the supporting product chemistry data.

SUMMARY OF FINDINGS:

Name of Active Ingredient(s):

PC CODE	Active Ingredient(% purity)	Reg. No.(source of AI)	NC of AI in product
117403	Clopyralid-oiamine (46.1% w/w a.i. nominal) [35.05% w/w a.e. basis]	62719-84	3.50%
123009	Topramezone (99.2%)	[REDACTED]	0.50%
121601	Acetochlor (95.4%)	[REDACTED]	30%

2. Has the registrant claimed substantial similarity to a registered product? [] Yes; [] No; [X] NA; if yes give the registration number of the cited product. EPA Reg.

3. All of the source materials of the active ingredient are derived from registered sources- [X] Yes [] No

4. All inert ingredients have been screened by CITAB (Inert Team) and found to be approved for the proposed label uses - [X] Yes; [] No

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5. Confidential Statement of Formula(s):

☒ Basic - Dated: December 13, 2021, Re-submitted - Dated:
☐ Alternate CSF No. Dated:
☐ Alternate CSF No. Dated:

Alternate CSF(s) complies with 40CFR§152.43: ☐ Yes; ☐ No; ☒ NA

6. Product label

a. Ingredient statement: Nominal concentration of AI listed on CSF(s) concurs with product label (PR Notice 91-2).

☐ Yes, ☒ No; if not, explain below: The label recites for the active ingredient Clopyralid MEA salt 2.67% vis-à-vis the CSF recites "(nominal a.i. (3.50)" and "[nominal a.e.] [2.7]"

Is the sub statement in compliance with PR Notice 97-6 (inert ingredient vs other ingredients)?

☒ Yes; ☐ No; if not, explain below

Metallic equivalent: ☐ Yes ☒ NA;
Soluble arsenic: ☐ Yes ☒ NA
Isomeric ratios: ☐ Yes ☒ NA
Acid Equivalent: ☒ Yes ☐ NA ; Clopyralid acid equivalent = 2.7%

b. Health related sub statements: Product contains?

Petroleum distillate at > 10%: ☐ Yes; ☒ No; ☐ NA

Methanol at > 4%: ☐ Yes; ☒ No; ☐ NA

Sodium nitrate/sodium nitrite ☐ Yes; ☒ No; ☐ NA

c. Physical chemical hazard statement: Product label requires a statement per 40 CFR §156.78 for: flammability, explosive potential or electric insulator breakdown?

☐ Yes ☒ No

Is the sub statement in compliance with PR Notice 98-6 (Total Release Fogger)?

☐ Yes; ☐ No; ☒ NA; if not, explain below

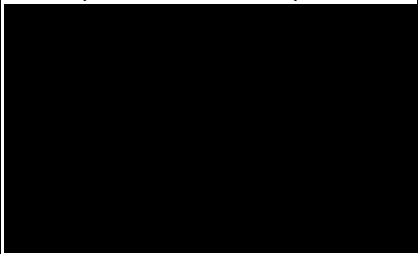
d. Label requires an additional Storage and Disposal statement: ☐ Yes ☒ No; if yes explain below:

Manufacturing process information may be entitled to confidential treatment

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7. Group A: Product Chemistry Data

CITAB's determination of the acceptability for the proposed product is listed in the tables below.

Guideline No.	Study Title		Data submitted		CITAB's Assessment of Data	MRID Nos. Cited
			Yes	No		
830.1550	Product Identity & Composition		X		A	51768901
830.1600	Description of materials used to produce the product		X		A	51768901
830.1650	Description of formulation process		X		A	51768901
830.1670			X		A	51768901
830.1700	NA Preliminary analysis				NA	
830.1750	Certified limits (158.350)	Standard certified limits				Basic CSF dated 5 Nov 2021 51768901
		Proposed Limits				
		Justification for wider limits	X		A	
830.1800	Enforcement analytical method		X		A	51768901 Validation provided with respect to linearity, accuracy and precision

A = Acceptance, N = Not Acceptable, G = Data Gap, W = Waiver Request, I = In Progress, NA = Not Applicable; U = Upgradeable.

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8. Group B:

Self-certified (SC) by applicant; dated: : ☐ Yes; ☒ No ☐ NA

Guideline No.	Study Title	Value or Qualitative Description	CITAB's Assessment of Data	MRID Nos.
830.6303	Physical State	Liquid at 20.6 °C	A	51661402
830.6314	Oxidation/Reduction	Non-oxidizing .No temperature change >5°C was observed	A	51661402
830.6315	Flammability	>115.0 °C Flash point	A	51661402
830.6316	Explosibility	TS is not explosive.	A	51661402
830.7000	pH	3.45 at 24 °C in a 1.00 % wt/wt solution	A	51661402
830.7100	Viscosity	Non-Newtonian fluid: viscosity decreasing with increasing shear rate.	A	51661402
830.7300	Density (Relative)	1.1024 g/mL at 20.02 °C	A	51661402
830.6317	Storage stability*	To be provided as part of the storage stability study. I	U	51661402
830.6320	Corrosion characteristics*	To be provided as part of the storage stability study. I	U	51661402

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*Fluorinated containers used during storage stability & corrosion characteristics studies:
☐ Yes; ☐ No; ☒ NA

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CONCLUSIONS:

CITAB has reviewed the product chemistry data submitted/cited for the end-use product and has concluded that:

A. Substantial similarity to the cited product (Reg. No.....) from Product chemistry view point

- ☐ Similar
- ☐ Not similar, give reasons
- ☐ Identical
- ☐ Not identical
- ☒ Not applicable

B. Confidential Statement of formula

1. Basic CSF (dated December 13, 2021)
 - ☒ Acceptable
 - ☐ Not Acceptable
 - ☐ Not Applicable
2. Alternate CSF No. (dated); Alt. No. (dated)
 - ☐ Acceptable
 - ☐ Not Acceptable
 - ☒ Not Applicable

If not acceptable give reasons:

C. Group A Product Chemistry

- ☒ Acceptable
- ☐ Not acceptable
- ☐ Acceptable with the exception of Guideline
- ☐ Not required
- ☐ Data cited; ☐ Acceptable; ☐ Not Acceptable (give reasons)

D. Group B Product chemistry data –

Self-certified by applicant: ☐ Yes; ☒ No

- ☐ Acceptable
- ☐ Not acceptable

☒ Acceptable with the exception of the guidelines: 830.6317 and 830.6320. The data on the guidelines 830.6317 and 830.6320 were not submitted. Registrant has the option to conduct accelerated studies (54°C for two weeks).

- ☐ Not required
- ☐ Data cited ; ☐ Acceptable; ☐ Not Acceptable;
- ☐ Waiver requests; ☐ Acceptable; ☐ Not Acceptable (give reasons)

E. Product Label/Draft Label

Recommendations – Yes ☒; No ☐; If yes, give recommendations below:

Note to PM: The label recites for the active ingredient Clopyralid MEA salt “2.67%” vis-à-vis the CSF recites “(nominal a.i. (3.50)” and “[nominal a.e.] [2.7]”. **The label should be changed to reflect the amount of the active ingredient recited in the CSF as 3.5%**

